DETAILED ACTION

1. Applicant's election without traverse of invention group II in the reply filed on September 1, 2010 is acknowledged.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 3, 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garry (WO 01/00829), in view of Balzarin et al., Taube et al. and applicants' admission that AZT has been shown to directly inhibit the MMTV RT enzyme as efficiently as the HIV RT. (page 2, lines 31-32) and the particularly salt or prod rug of tenofovir was FDA approved therapeutical agents at the time the claimed invention was made. (page 3, lines 26-34).

3. Garry teaches a method of treating MTV associated breast cancer comprising administering to the patient a composition comprising one or more retroviral inhibitors, such as protease and reverse transcriptase inhibitors. Garry particularly teaches that HIV integrase, protease, and reverse transcriptase inhibitors are useful for the method. See, the entire document, particularly, page 19, lines 5-30.

4. Garry does not teach expressly the employment of tenofovir for treatment of MTV associated breast cancer.

5. However, Balzarini et al. teaches that tenofovir (PMPA) is known to have antiretrovirus activity against various retroviruses, including HIV. See, particularly, the abstract, and table 2 at

page 2188. Taube et al. teaches that MMTV reverse transcriptase (RT) exhibits a high sensitivity to nucleoside triphosphate analogues, such as AZT triphosphate and DDT triphosphate, (which are known to be potent inhibitors of HIV RTs and are being used as the major anti-AIDS drugs). See, particularly the abstract and table 4 at pages 585. Applicants admitted that AZT, a well known reverse transcriptase inhibitor against HIV, has been shown to directly inhibit the MMTV RT enzyme as efficiently as the HIV RT. (page 2) and the particularly salt or prodrug of tenofovir was FDA approved therapeutical agents at the time the claimed invention was made. (page 3, lines 15-23).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ FDA approved tenofovir, and other known retroviral inhibitors, such as AZT, in Garry's method for treatment of mammary tumor virus associated breast cancer.

A person of ordinary skill in the art would have been motivated to employ FDA approved tenofovir, and other known retroviral inhibitors, such as AZT, in Garry's method for treatment of mammary tumor virus associated breast cancer because tenofovir is a known broad spectrum antiretroviral agent, and known reverse transcriptase inhibitors against HIV have been shown to directly inhibit the MMTV RT enzyme as efficiently as the HIV RT. One of ordinary skill in the art would have reasonably expected that tenofovir be useful against MMTV or HHMMTV as efficiently as the HIV. As to the recitation of "MMTV-like", it is contend that Human MTV would meet this limitation (Human MTV is a homologue of MMTV). See, page 3, the last paragraph bridging to page 4 in Garry et al.

Remarks

6. Applicants' remarks regarding the above rejections have been fully considered, but are not persuasive. Applicants contend that the claims are not obvious over the cited references because different nucleoside analogues exhibit significantly different potencies, and PMPApp (the metabolite of tenofovir) is much more potent than 3TCppp and FTCppp. The arguments are not persuasive. Particularly, it is known that retroviral inhibitors are useful for treating MTV associated breast cancer and tenofovir is one of few clinically approved retroviral inhibitors. It would have been obvious to one of ordinary skill in the art to use tenofovir in Garry's method. The difference among the retroviral inhibitors herein listed is difference in degree and is not considered to be sufficient for supporting a patentably distinct feature. Further, in KSR vs. Teleflex, the court states:

"When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. **If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.** In that instance the fact that a combination was obvious to try might show it was obvious under section 103." In the instant case, retroviral inhibitors are known to be useful against MTV, and the number of clinically approved retroviral inhibitors is very limited. The employment of tenofovir as a potent retroviral inhibitor against MTV would have been a case of obvious to try.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1627